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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **Benjamin W. Boldt and Dennis Roscetti**

Serial No.: 09/109,119

Filed: 06/30/98

Group Art Unit: 1655

Examiner: **Jeanine Goldberg**

For: **A Process For Detecting A Known Sequence In Genomic DNA**

AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

This Amendment responds to the Office Action dated July 31, 2001. Kindly amend the application as follows:

In the Claims:

Please cancel claims 17-20 and amend claims 1 and 13 as follows:

A clean version of each replacement claim is submitted below. Please enter each claim.

Subst 1. (Amended) A process for testing genomic DNA to determine if at least one base is present, comprising:

a. making a solution comprising the genomic DNA;
b. adding a primer that hybridizes to a targeted sequence of the genomic DNA wherein the primer 3' nucleotide will hybridize and extend along the genomic DNA if the base is present;
c. mixing a DNA polymerase into the solution;
d. amplifying the targeted sequence of the genomic DNA if the base is present;
e. capturing amplified sequence to a solid support wherein the solid support contains probes that hybridize to amplified product having the base; and,
f. detecting amplified targeted sequence if the base is present.

13. (Amended) A process for detecting a base in a targeted sequence of genomic DNA, comprising:

a. obtaining the genomic DNA;
b. mixing the genomic DNA with a primer that hybridizes to the targeted sequence of the genomic DNA wherein the primer 3' end nucleotide hybridizes to the genomic DNA if the base is present;
c. amplifying the targeted sequence of the genomic DNA if the base is present;
d. capturing amplified polynucleotide strands to a solid support wherein the solid support contains probes that hybridize to amplified product having the base; and,
e. detecting amplified targeted sequence if the base is present.

REMARKS

Rejection of claims 17-20 under 35 U.S.C. 102-103:

The §102 and §103 rejections to claims 17-20 are obviated by the cancellation of these claims.

Objection to the Specification under 35 U.S.C. 112:

In the Office Action, on pages 4 and 5, claims 1-16 have been rejected under §112.

Applicants have amended independent claims 1 and 13 to remove the terminology objected to in the Office Action.

Accordingly, Applicants believe that the §112 rejections are obviated by the amendments.

Rejection of claims 1, 2 and 13 under 35 U.S.C. 102:

Claims 1, 2, 13 have been rejected under §102 as being anticipated by Newton et al. Applicants respectfully disagree.

Applicants' processes "capture amplified sequence to a solid support wherein the solid support contains probes that hybridize to amplified sequence having the base" (as stated in Applicant's step e). In contrast, the Newton et al. reference does not capture amplified polynucleotide strands to a solid support. Newton's primer sequences hybridize to probes attached to the solid support. When primer sequences are complementary to and hybridize to the probe, a severe competition problem occurs since there will be many more non-amplified primers available for hybridization than primers that have initiated an amplified product. More non-amplified primers will hybridize to the probe than primers that have initiated an amplification product. Therefore, Newton's non-amplified primers create detection problems. Additionally, the Newton et al. reference describes a primer that purposely blocks complementary strand extension to itself. The reference describes adding compounds near the primer 3' ends to prevent opposing polymerization.

In contrast to Newton's methods, Applicants' processes capture only amplified sequences that are not part of the primer sequence. Therefore, all hybridization to the probe is amplified sequences and not primer sequences.

Applicants believe that the rejection has been obviated. Therefore claims 1 and 13 along with their dependent claims are believed to be allowable.

Rejection of claims 1-16 under 35 U.S.C. 103:

Claims 1-16 have been rejected under §103 as being obvious using Newton et al. and Monforte et al. as references. Applicants respectfully disagree.

Using the arguments stated above, neither Newton et al. nor Monforte et al. are selective for amplified product. Both references attach the primer to the plate whether or not the primer has undergone polymerization. They do not teach the attachment of amplified product. For example: during amplification perhaps 10% of the primers may polymerize along a target strand forming amplified product. However, 90% of the primers remain unamplified. Since both of the cited references teach attaching the primer sequences to the solid support, only 10% of the available solid support sites will contain amplified DNA. The other 90% will contain primers only.

Conversely, Applicants' process utilizes the sequence of amplified product for attachment, not primer sequence. Therefore, if there is amplified product, 100% of the available attachment sites will contain amplified product as opposed to 10% in the cited art. However, if no product is amplified, none of the sites will contain product or primer. This is a significant improvement in detection capability.

The Office Action's objections and rejections are believed to be overcome by this Amendment and Response. In view of Applicants' amendment and discussion, it is submitted that the claims 1-16 should be allowable and Applicants respectfully request an early notice to such effect.

Respectfully submitted,

Mark K. Johnson Reg. No. 35,909
P.O. Box 510644
New Berlin, WI 53151-0644
(262) 821-5690

I hereby certify that this correspondence is being deposited with the United States Postal Service as EXPRESS MAIL - POST OFFICE TO ADDRESSEE, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on 1/29/02.

Signature